



Investigators - Introduction and eDiary



Agenda

INSPIRING RESPIRATORY HEALTH

- nSpire services
- Site Equipment
- Connectivity & Synchronization
- Log on & User Accounts
- Certification Process
- Subject entry
- The PiKoLogic eDiary
- The PiKo meter
- Using the eDiary
- AC060A202 on the eDiary
- Assigning eDiary to patient
- Q&A

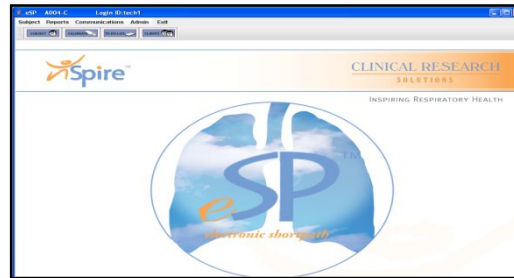


nSpire Services

INSPIRING RESPIRATORY HEALTH



We train and certify technicians on our equipment and the protocol requirements



We supply measurement devices with our custom eSP software, configured to the sponsor protocol



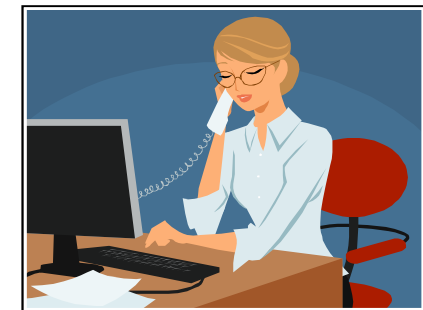
Data is transferred from sites to our centralized secure servers



Test are reviewed for Quality



Final Data is cleaned and sent to Sponsor

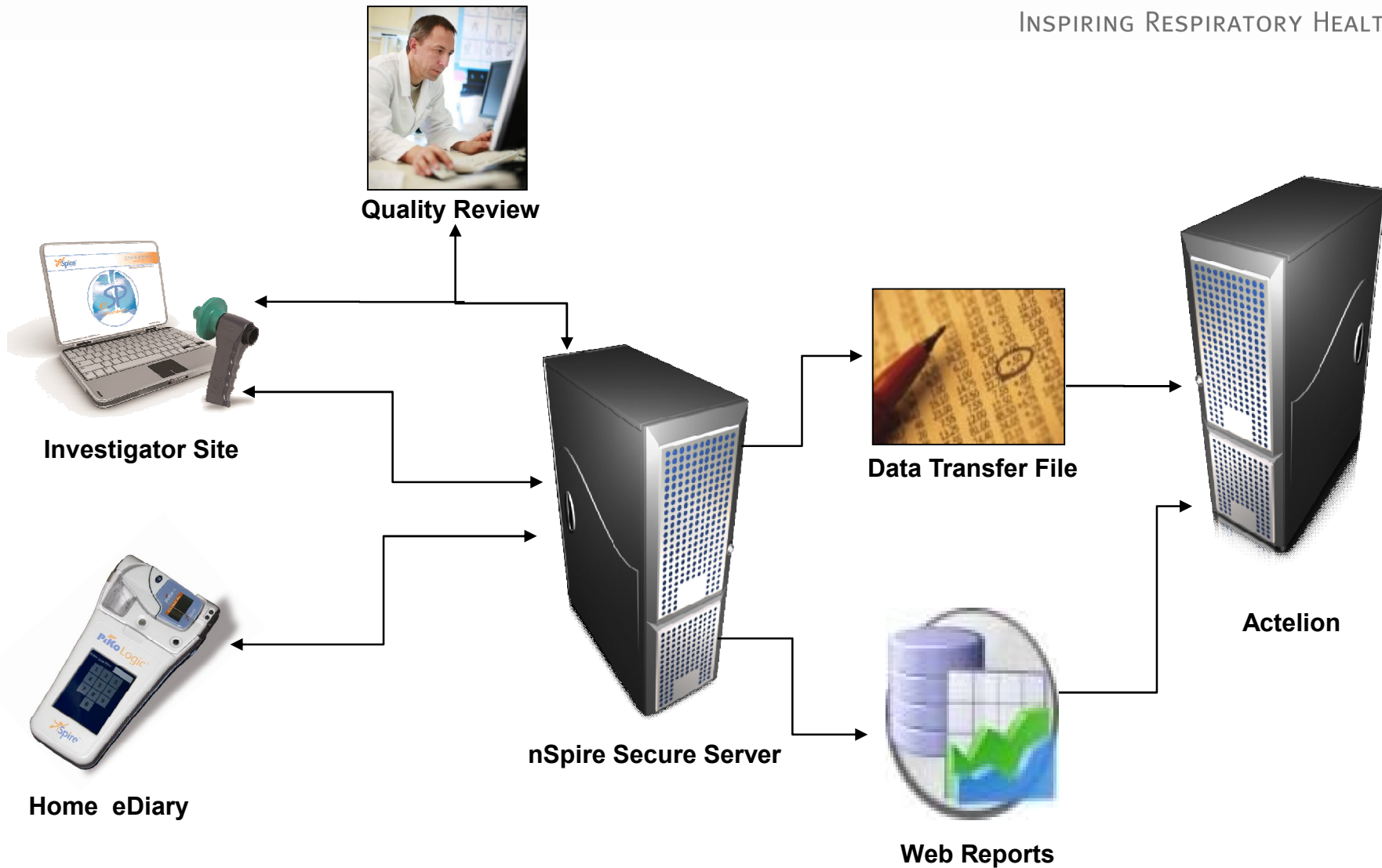


We provide clinical and technical support 24/7/365



Overview of nSpire System

INSPIRING RESPIRATORY HEALTH



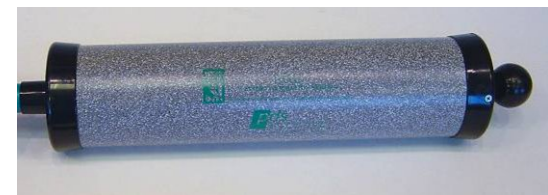


Spirometry System

INSPIRING RESPIRATORY HEALTH

The equipment includes:

- Laptop computer
- KoKo spirometer
- KoKo antibacterial/antiviral filters
- PiKoLogic eDiaries
- Piko1 Electronic Peak Flow Meters
- 3 liter calibration syringe
- Color printer
- Weather Station
- User Guides
- Certification documents





eSP Synchronization

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Synchronization is two way communication between the site and nSpire.

It transmits:

- data
- eQueries
- software updates

Synchronization is automatic during system start up and when eSP is closed. The system must be connected to the internet via either:

- Analogue line
- LAN
- WLAN
- Cellular data card



If an internet connection is used, firewall access may need to be configured –a list of all required open firewall ports is in the System User Guide.



The Opening Screen

INSPIRING RESPIRATORY HEALTH

Research Spirometry Home (V1.0.0.30)

View Comms Utilities Help

 **Opening Research Spirometry** **CLINICAL RESEARCH SOLUTIONS**

for studies: **Control** **INSPIRING RESPIRATORY HEALTH**

NETWORK

Looking for Networks 8

Information

Last Synchronization
14 October at 12:26:35 PM

192.168.2.2

MESSAGES

PROGRESS

Steps

- ☒ Network
- ☐ Internet
- ☐ nSpire-link
- ☐ Antivirus
- ☐ Time update
- ☐ Synchronization

5

ADVANCED DETAIL

1 | 2

Windows IP Configuration

Ethernet adapter Wireless Network Connection:

Connection-specific DNS Suffix . : StudyC
IP Address : 192.168.2.2
Subnet Mask : 255.255.255.0
Default Gateway : 192.168.2.1

Ethernet adapter Local Area Connection:

Media State : Media disconnected

nSpire Consumer Health:

nSpire Healthcare Providers




nSpire Clinical Trial Sponsors

Please Enter Your Login Information.

Study ID:

Login ID:

Password:

The login screen has a grey background. It contains three text input fields for "Study ID", "Login ID", and "Password". Below these fields are three buttons: "LOG ON" with a hand cursor icon, "Clear Reset" with a yellow circular arrow icon, and "CHANGE PASSWORD" with a padlock icon.

When Synchronization is complete the eSP login screen will appear.



Administrator Accounts

- An administrator is designated by the PI and is responsible for setting up the technician accounts.
- The PI holds an administrator account.
- No testing can be performed from an administrator account.

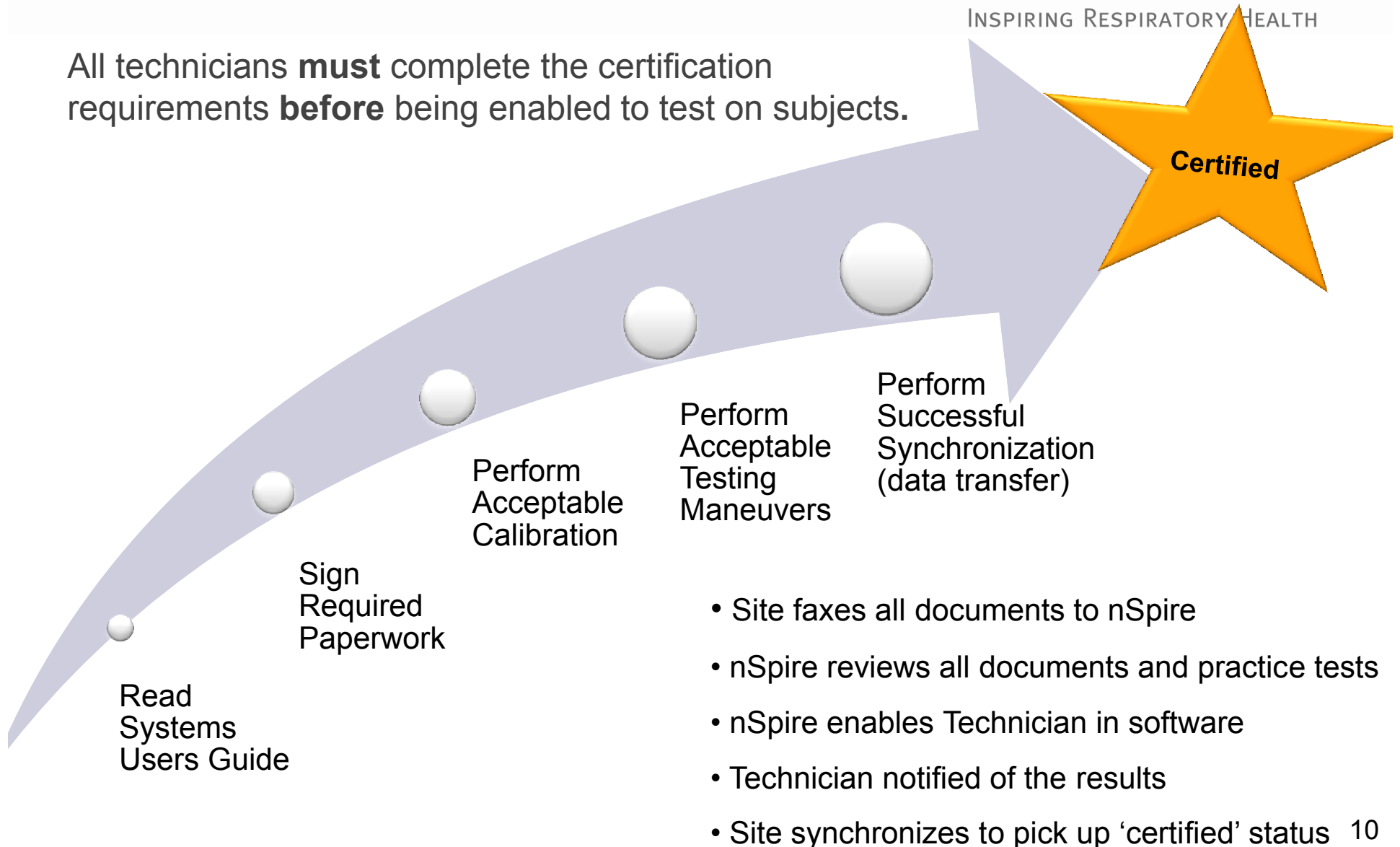
Technician Accounts

- Technicians are responsible for performing the subject testing.
- If an administrator is to perform subject testing, they must also set up a technician account.

Certification Requirements

All technicians **must** complete the certification requirements **before** being enabled to test on subjects.

INSPIRING RESPIRATORY HEALTH






Certification Requirements

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Required Documents:

- Investigator Statement
- Security Statement
- Technician Checklist
- Acceptable Calibration
- Acceptable Spirometry

 Investigator Statement	
INSPIRING RESPIRATORY HEALTH	
Protocol: P05575	
Dear Investigator,	
In compliance with United States FDA's 21 CFR Part 11 regulations, this letter informs you of your responsibilities with regard to the personnel using the eSP Spirometry System.	
21 CFR 11.10 states that procedures should be in place to ensure that persons who develop, maintain, or use electronic record/electronic signature systems (the eSP Spirometry System) have the education, training, and experience to perform their assigned tasks. The regulations also state that policies should be employed that hold individuals accountable and responsible for actions initiated under their electronic signature.	
With this in mind, nSpire Health asks that when the system is received at your site, you ensure that all study personnel involved with this project are familiar with the study-specific System User Guide. Electronic data clarification (eQuery) requests from nSpire Health require a response from site personnel that may result in data changes. It is the responsibility of the site personnel and the Investigator to ensure that the response to the eQuery is timely and accurate.	
If anyone has questions regarding the eSP Spirometry System, they should contact the nSpire Health Helpdesk.	
A site Administrator will be responsible for creating and maintaining User Accounts. You may choose to act as the Administrator or you may delegate this responsibility to a member of your staff. If the Administrator responsibilities are delegated, you must designate that person in the lower portion of this page. Please note that the Administrator will also need a Technician User Account if they are to perform testing. Please store this Investigator Statement with your regulatory binder.	
We appreciate your efforts to make this study successful.	
Sincerely,	
nSpire Health	
I, the undersigned, as Principal Investigator participating in the above noted clinical trial, acknowledge that:	
(a) I understand the information presented above;	
(b) I will be responsible for ensuring that all study personnel are familiar with the study-specific System User Guide; and;	
(c) I have had an opportunity to ask and have received answers to any questions I may have had.	
Designated Site Administrator Name (please print): _____	
Principal Investigator Name (please print): _____	
Principal Investigator Signature: _____ Date: _____	
Upon completion, please return this document to nSpire Health. It must be received by nSpire Health prior to subject testing.	
Fax: +1 800 916 4737 (or use the toll free access number provided)	
Investigator Statement, eSP System	
V1.0	



The SUG – System User Guide

INSPIRING RESPIRATORY HEALTH

A brief look
at the
content



eSP Home Screen

INSPIRING RESPIRATORY HEALTH





Subject entry screen

INSPIRING RESPIRATORY HEALTH

eSP CONTROL Login ID:tech1

Subject Entry

FIND

PIKO

TEST

nSpire Site ID: 100

Subject #: XXXXXXXXXX

Age:

Gender: Male

Height(cm):

PikoLogic Time zone: (GMT+01:00) GMT+1

DOB (DD/MM/YYYY):

Position: Sitting

Race/Ethnicity:

Weight(kg):

PiKoLogic Language:

Type Test	Visit Name	Visit#	Interval Name	Interval#	QA Status	Stage Name	Stage#	Seq Num	Test Da

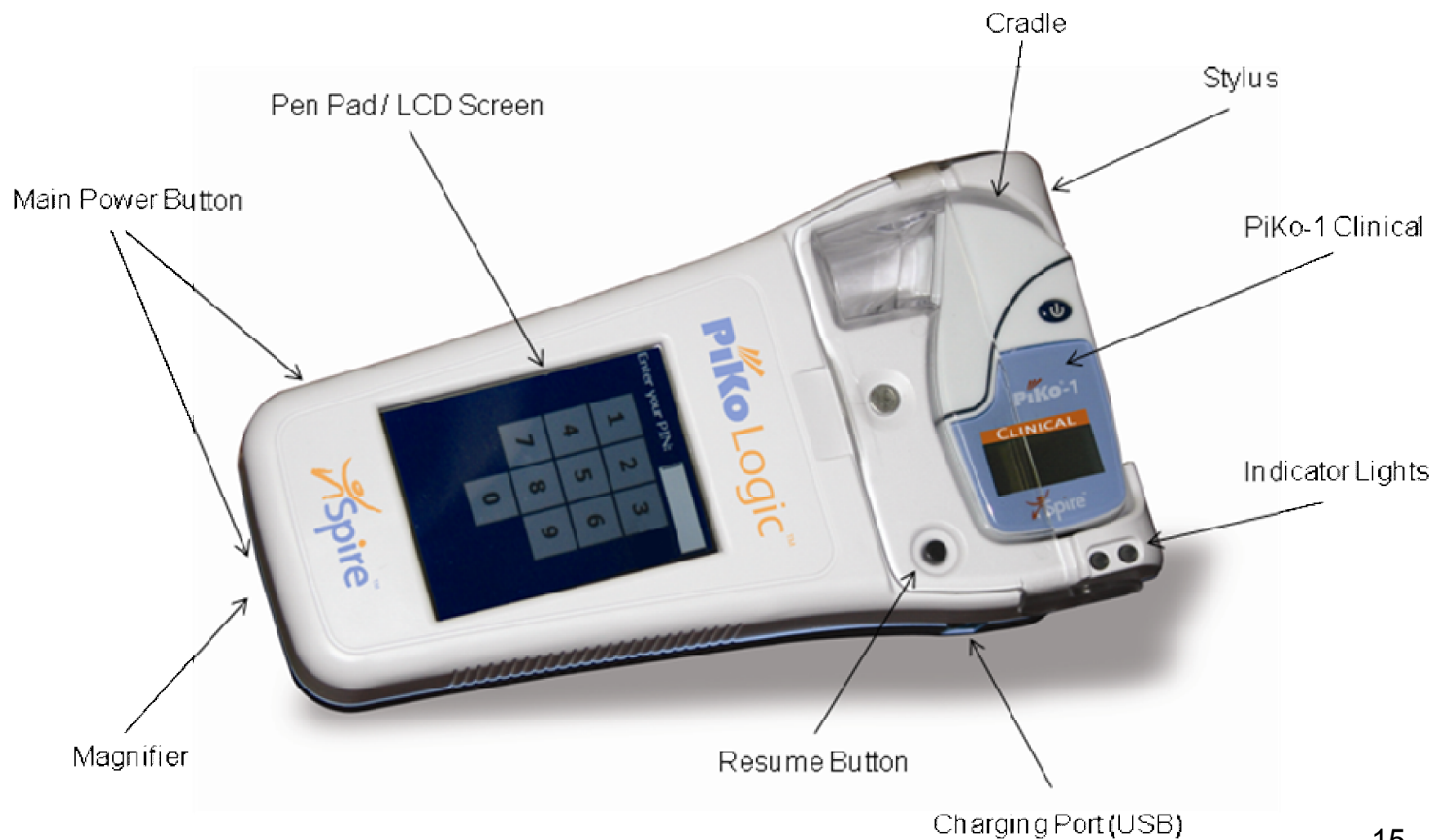
SUBMIT **Clear Reset** **HOME**

start eSP CONTROL ... 01:07



The PiKo Logic eDiary

INSPIRING RESPIRATORY HEALTH





The PiKo PEF and FEV1 meter

INSPIRING RESPIRATORY HEALTH

- Morning & Evening Peak Flow Measurements
- PiKo is single patient use.
- Once assigned to a patient, it cannot be reassigned to another.
- Data is Downloaded to the PiKoLogic eDiary after each use
- Single On button – turns itself off automatically
- Shows PEF and FEV after each effort





Morning

- Asthma symptoms
- Rescue medication questions
- PEF measurements
- Medication instructions

Evening

- Study Drug questions
- Meal times
- Asthma symptoms
- Rescue medication questions
- PEF measurements
- Medication instructions

Can be configured in many **languages**.

Configurable **alarms** remind subjects to make diary entries.

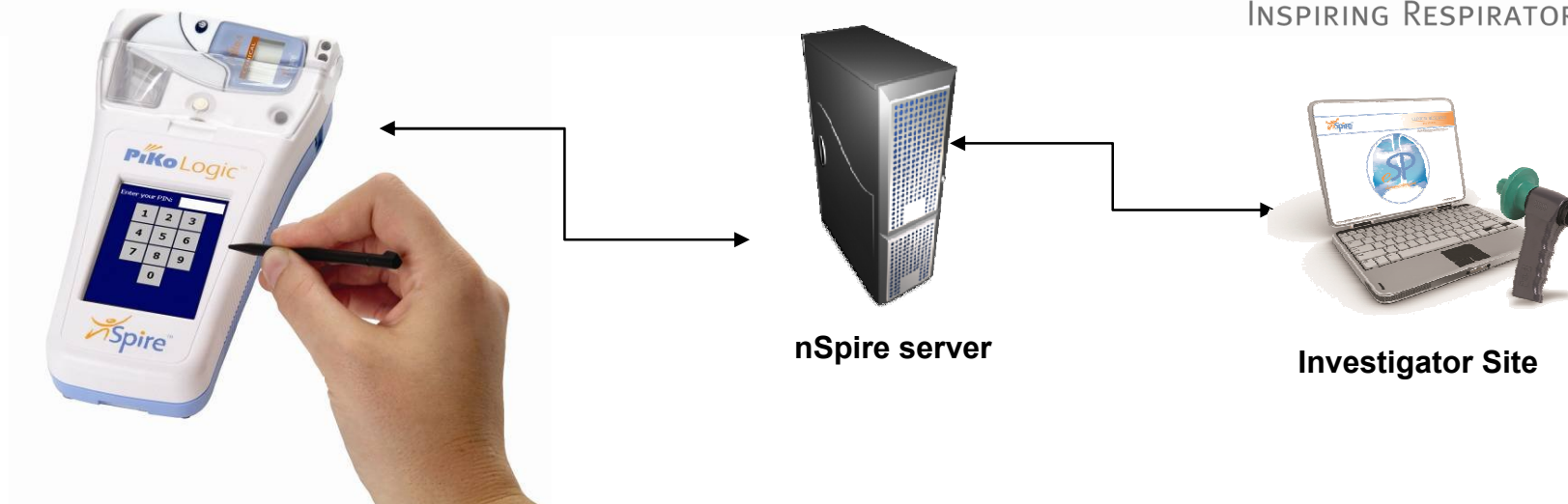
PikoLogic is **single patient use**. Once assigned to a patient, it cannot be reassigned to another.

Diary Questions and PEF data are stored on PikoLogic *and* sent to nSpire server over cellular network.



Data sent to nSpire Server

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After data from PikoLogic is transmitted to nSpire server, site laptop must synchronize with nSpire server to download and review data.

Reports will detail answers to diary questions and PEF data.



eDiary Requirements

INSPIRING RESPIRATORY HEALTH

- 2 sessions daily:
 - 4 am (04:00) to noon (12:00)
 - 7 pm (19:00) to 2 am (02:00)
- A session is complete when:
 - All questions answered, and
 - 3 spirometry efforts performed
- A session is usually performed following the alarm, but can be performed anytime during the session-time window by pressing PiKoLogic resume button
- A spirometry effort is usable if no error (e.g. cough, too short a blow, etc.) is detected by PiKo
- If fewer than 3 usable efforts are blown, subject will be prompted to do more, up to a maximum of 5 efforts



Alarms

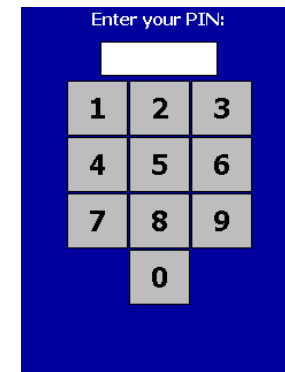
INSPIRING RESPIRATORY HEALTH

- Alarms implemented for both sessions
- Subject may adjust alarm time to personal preference:
 - Morning session alarm between 7 am (07:00) and 11 am (11:00)
 - Evening session alarm between 8 pm (20:00) and 12 midnight (00:00)
- 2 additional reminder alarms at 30 minutes and 60 minutes after initial alarm will sound if session is not completed. Example:
 - if alarm goes off at 9:00am and the session is not completed, a reminder alarm occurs at 9:30 am (09:30) and 10:00 am (10:00)



- PikoLogic will automatically 'light-up' and alarm when a diary session is due, prompting for a PIN

- PIN will be required for each subject (min 4 digits)
- PiKoLogic displays best PEF and FEV1 results of each session in Liters/minute BTPS, corrected for altitude, which enhances accuracy



- English
- German
- Spanish (US)
- Bulgarian
- Hungarian
- Hebrew
- Polish
- Russian
- Serbian
- Swedish
- Afrikaans
- Ukrainian
- Malay (for Singapore)
- Chinese (for Singapore)

Choice of *language required* should be made when entering subject demographic data in eSP



Session Questions

INSPIRING RESPIRATORY HEALTH

- Different morning and evening session questions
- Morning questions capture:
 - Night time asthma symptoms
 - Quantity and time asthma reliever medication is taken
 - Time study medication is taken
- Evening questions capture:
 - Time of breakfast and dinner
 - Day time asthma symptoms
 - Quantity and time asthma reliever medication is taken
 - Time study medication is taken



Messages

INSPIRING RESPIRATORY HEALTH

- Morning session:
 - On visit day:
 - Do not take medication and do not eat. Contact study doctor if asthma reliever medication was taken within 5 hours.
 - On non-visit day:
 - Do not eat for 30 minutes after medication
- Evening session:
 - Contact study doctor if “asthma deterioration” is detected



Asthma Deterioration

INSPIRING RESPIRATORY HEALTH

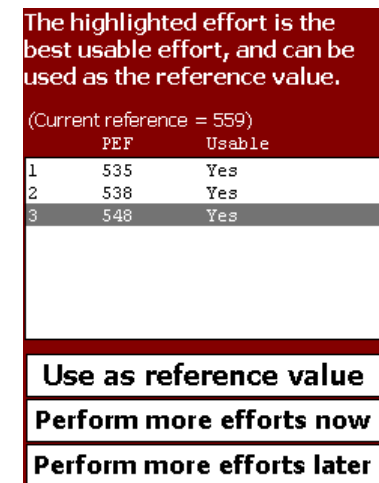
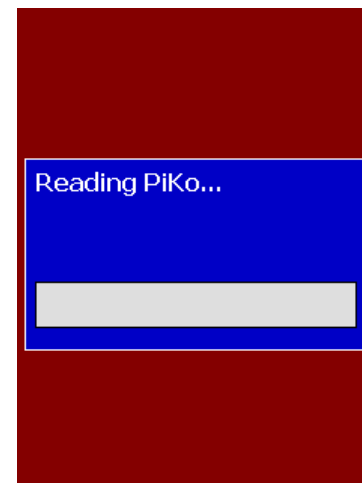
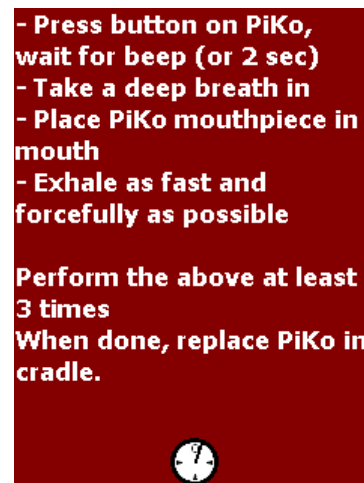
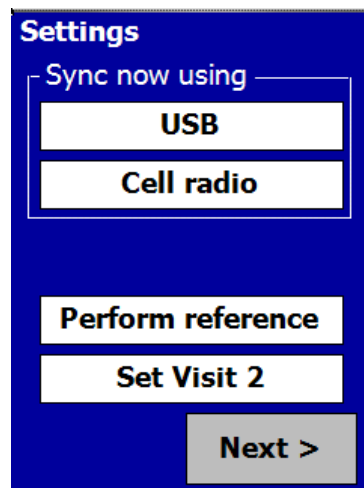
- Asthma Deterioration is detected by algorithm programmed into PiKoLogic.
- If any of the following conditions are true:
 - 3 or more PEFs in last 4 sessions are each less than 70% of baseline. NOTE: only checked in nighttime session.
 - SABA count>8 today AND SABA count>8 yesterday. Each 'day' being the sum of counts in both sessions.
 - Symptom Score>6 today AND Symptom Score>6 yesterday. Each day being the sum of morning and nighttime symptom scores. The symptom score is the number shown in front of each response to the symptom questions.
- An email alert will also be sent to site investigator, following successful data transmission to nSpire Health server.



PEF Baseline

INSPIRING RESPIRATORY HEALTH

- At first visit, PEF baseline will be determined from best PEF using PiKo, under technician supervision.
- Enter Tech Settings Screen using PIN:121703
- Tap 'Perform reference' option



Note that PiKoLogic screen color is different (red) for baseline determination

- Tap 'Use as reference value' when acceptable effort performed



PEF Baseline

INSPIRING RESPIRATORY HEALTH

- A red “**NO REFERENCE VALUE**” is shown on the status screen if baseline is not set.

Now:


10:05 AM Monday 9/27/10
(GMT-07:00) Mountain Time Daylight Time
(US, Canada)


Next alarm:

9:00 PM Monday 9/27/10

NO REFERENCE VALUE

AC power: Connected

PiKoLogic battery: 

PiKo battery: 

Cell radio: Enabled

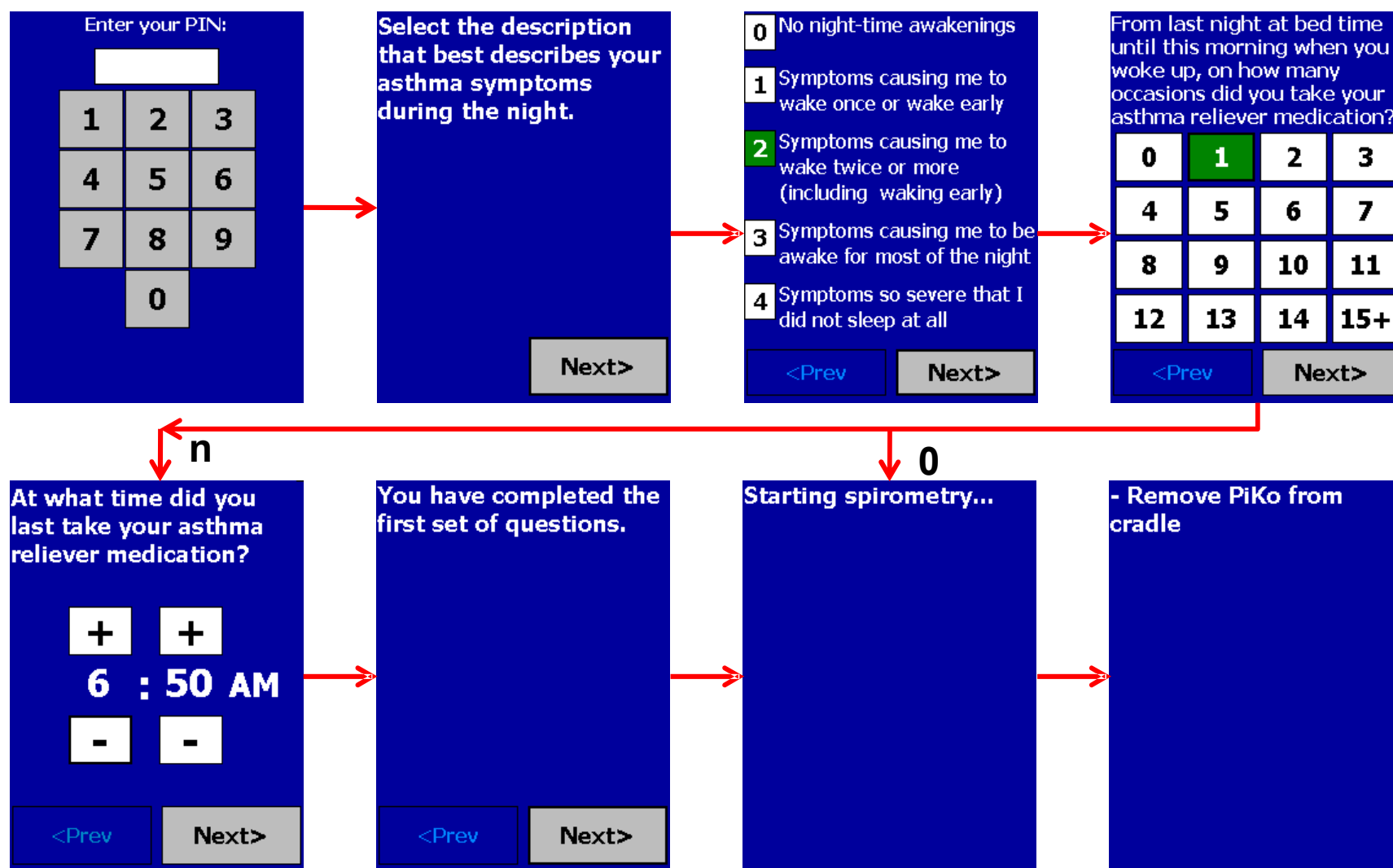
[Settings](#)



PiKoLogic Screens – Morning

(as between V1 and V2)

INSPIRING RESPIRATORY HEALTH

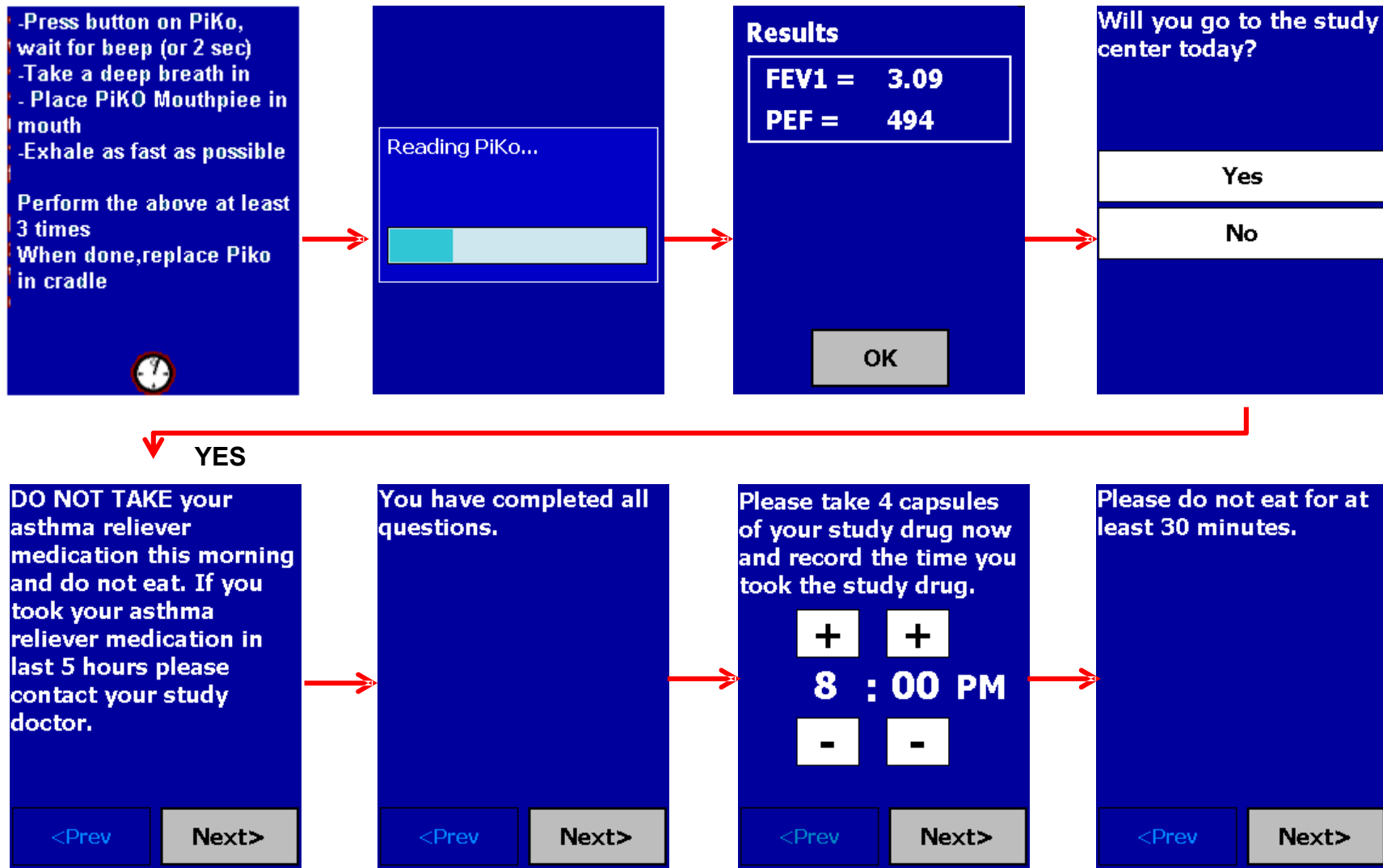




PiKoLogic Screens – Morning

(continued)

INSPIRING RESPIRATORY HEALTH

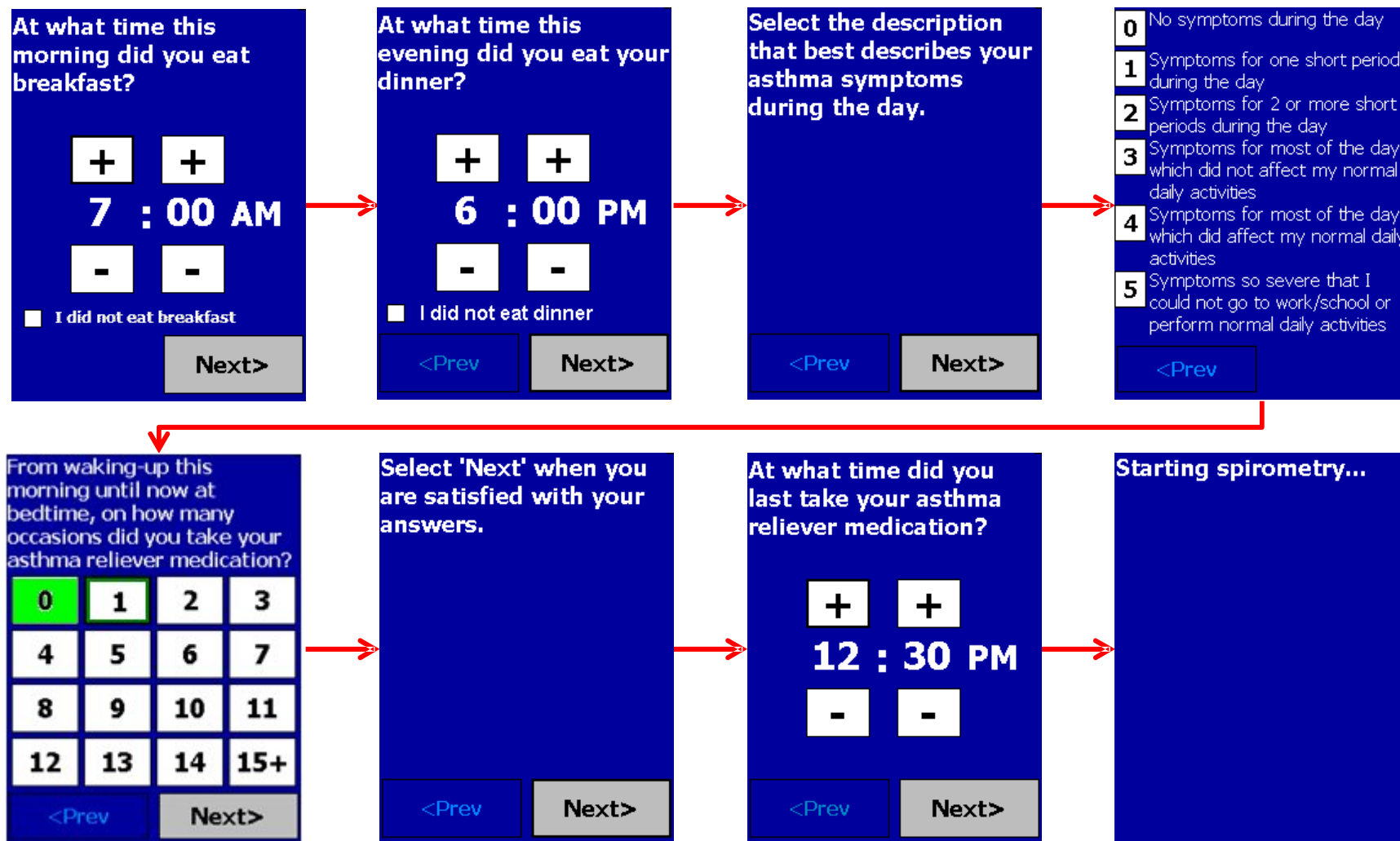




PiKoLogic Screens – Nighttime

(non visit Day)

INSPIRING RESPIRATORY HEALTH

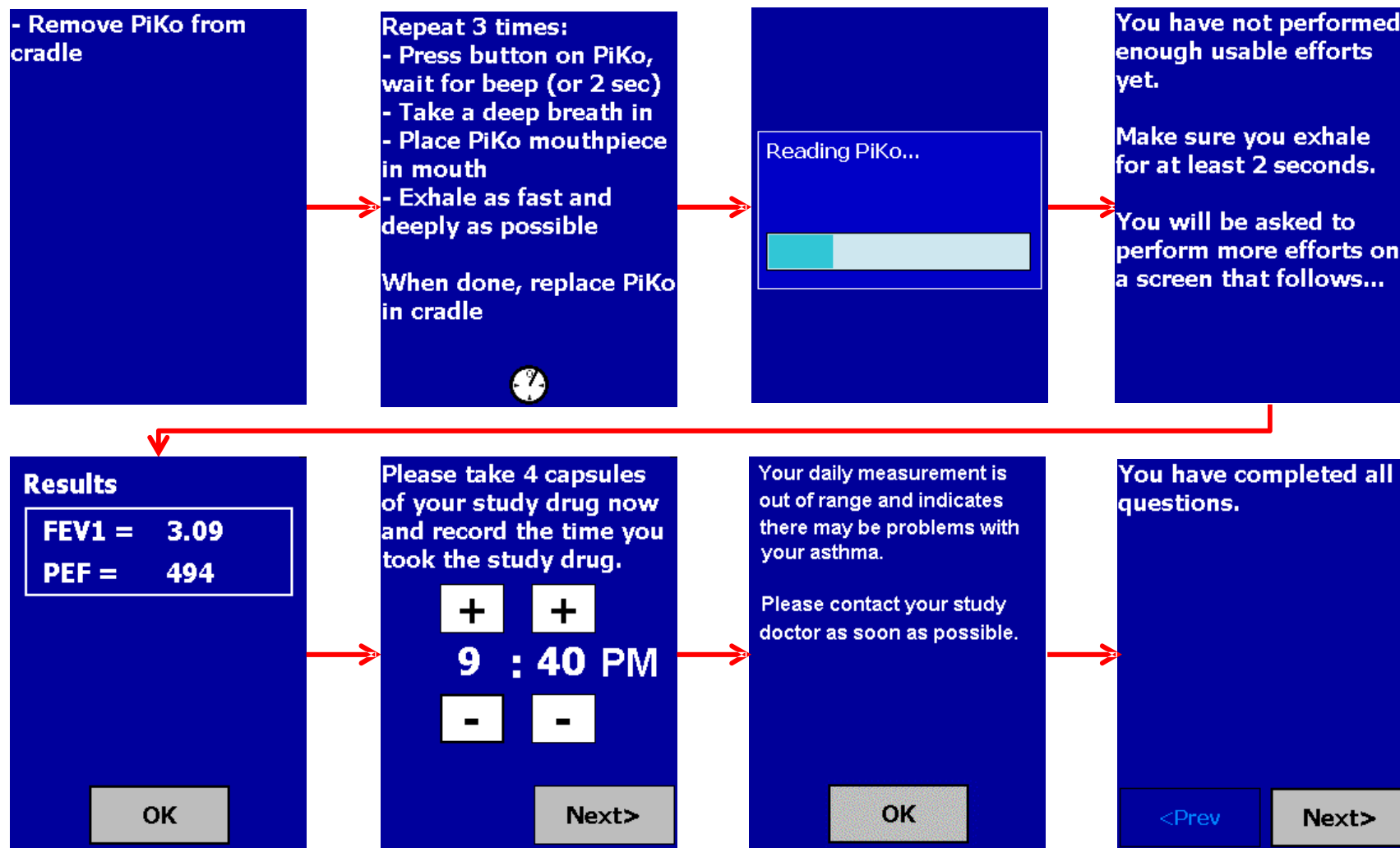




PiKoLogic Screens – Nighttime

(continued)

INSPIRING RESPIRATORY HEALTH





Visit two setting

INSPIRING RESPIRATORY HEALTH

- In order to have the diary prompt subject to take Study Drug, subsequent to V2, the tech must set the 'V2 *completed*' setting at Visit 2
- Enter Tech Settings Screen using PIN:121703
- Tap 'Set Visit 2' option
- **If this is NOT performed on V2 subject will need to return next morning with diary to have this done**

A screenshot of a blue settings screen. At the top is the title 'Settings'. Below it is a section 'Sync now using' with two options: 'USB' and 'Cell radio'. Further down are two more options: 'Perform reference' and 'Set Visit 2'. At the bottom right is a grey button labeled 'Next >'.

Settings

Sync now using

USB

Cell radio

Perform reference

Set Visit 2

Next >



ASSIGNING PIKOLOGIC & PIKO TO SUBJECT

INSPIRING RESPIRATORY HEALTH

Pre-requisite

The site computer is connected to internet

You are familiar with eSP

You have created (or know how to create)
a subject in eSP

PiKoLogic is charged and powered up

Batteries installed in PiKo-1, and it is in
place in the PikoLogic

Piko-1 does not need to be turned on



Step 1 – Using Computer

INSPIRING RESPIRATORY HEALTH

- Create a new or recall an existing subject
- Make sure all changes are followed by clicking **Submit**
- While in **Subject** screen, click **PiKo** to advance to **PiKoLogic Graph** screen
- Enter login password
- Connect PiKoLogic to computer using USB cable





Entering a new Subject

INSPIRING RESPIRATORY HEALTH

- Accurately enter the subject demographic information, required by the protocol.
- Click **SUBMIT** to save.
- After these details have been correctly entered, the Test option becomes available.

The screenshot shows the 'Subject Entry' form in the Spire system. At the top, there are three buttons: 'FIND' (active), 'PKG', and 'TEST' (disabled). Below these are input fields for 'nSpire Site ID' (value: 23), 'Randomization ID', 'Screening ID' (redacted), 'Age', 'Gender' (value: Male), and 'Height(cm)'. To the right, there are fields for 'DOB:(dd/mm/yyyy)', 'Position' (value: Sitting), 'Race', 'Weight(kg)', and 'PIKoLogic Language' (value: English/United Kingdom). At the bottom, there is a table with columns: Type Test, Visit Name, Visit#, Interval Name, Interval#, QA Status, Stage Name, Stage#, Seq Num, and Test Date. The table body is currently empty and highlighted in blue. Below the table are three buttons: 'SUBMIT', 'Clear Reset', and 'HOME'.



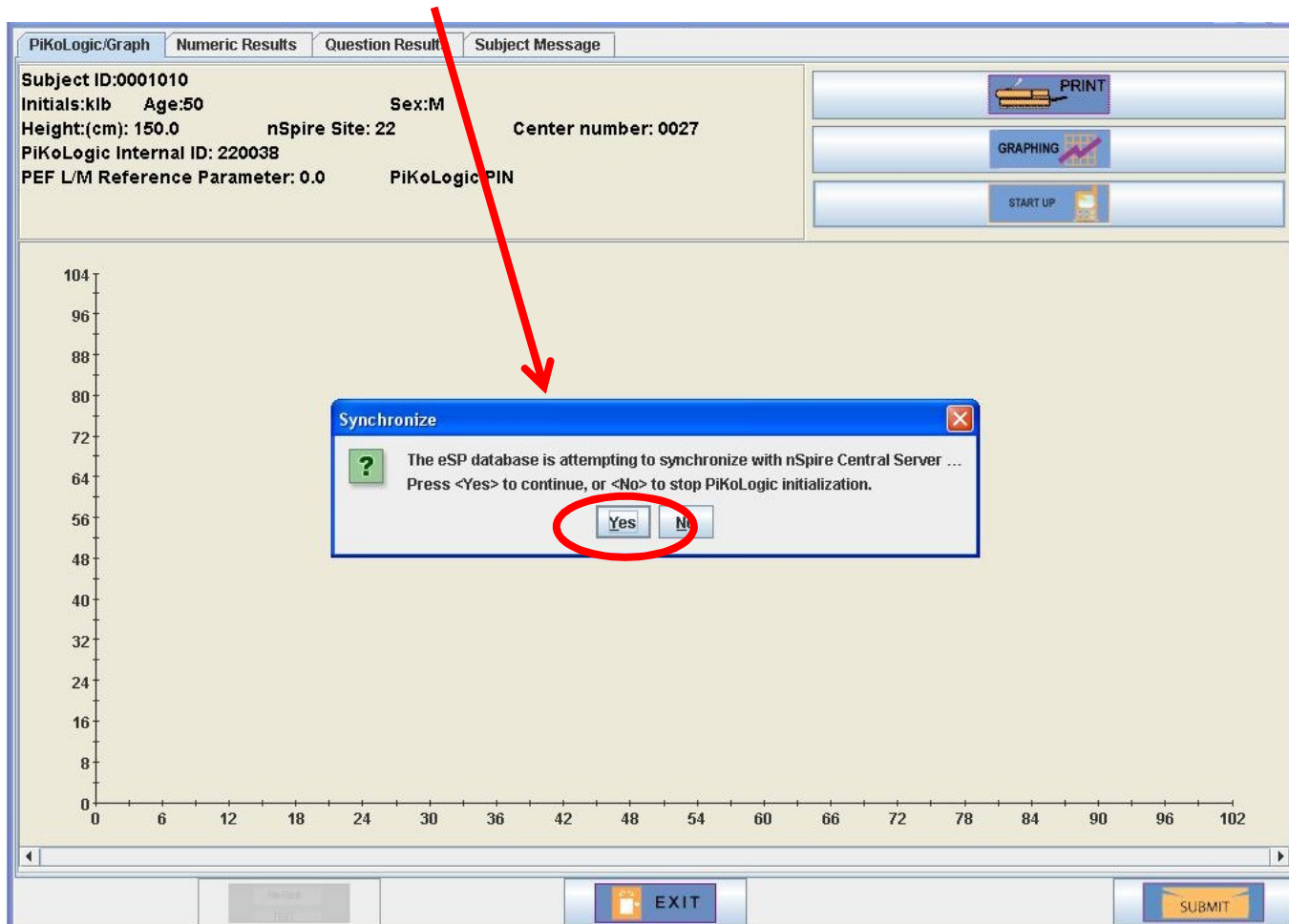
Step 2A

INSPIRING RESPIRATORY HEALTH

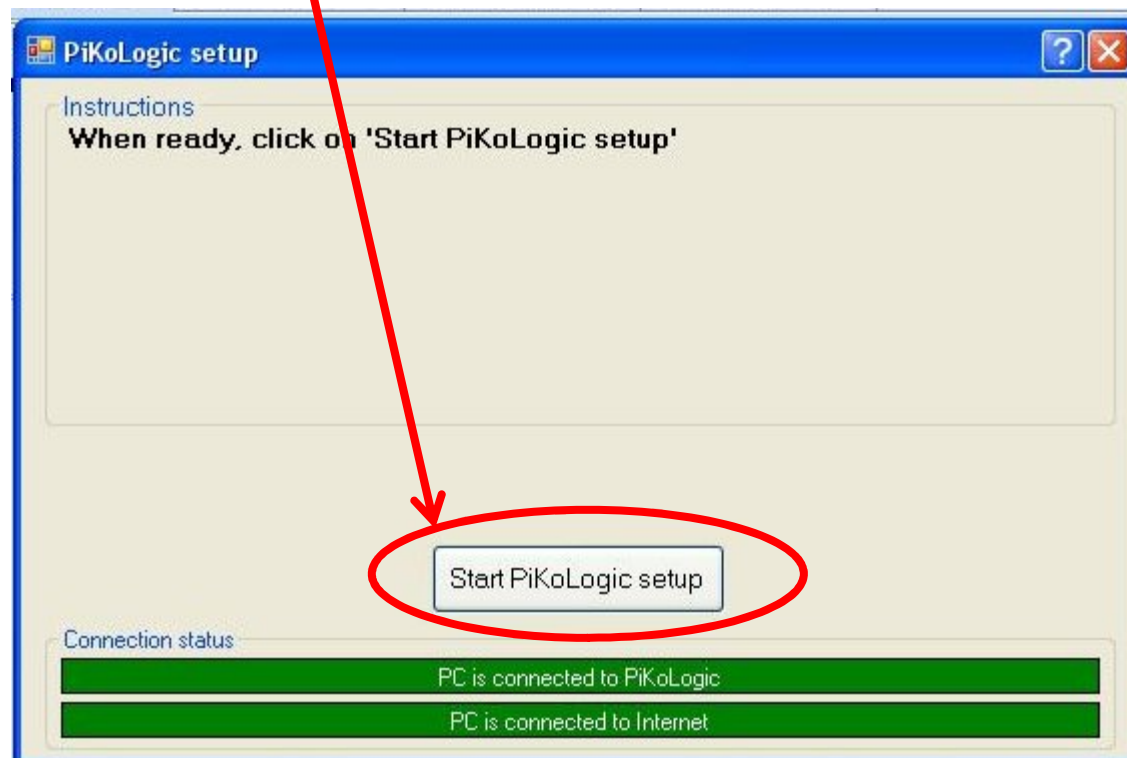
Click START UP

The screenshot shows the nSpire software interface. At the top, a blue header bar contains the text 'eSP P05575 Selected Screening ID: S-00079 nSpire Site ID: 72 Login ID:tech1'. Below this is a tabbed menu with 'PiKoLogic/Graph' selected. The main area is divided into two sections. The left section displays patient information: 'Screening ID:S-00079', 'Age:47', 'Gender:M', 'Height:(cm): 168.0', 'Weight:(kg): 66.0', 'nSpire Site: 72', 'Center number: 0027', 'PiKoLogic Internal ID: 720024', 'NO REF Reference Parameter: 0.0', and 'PiKoLogic PIN'. The right section contains three buttons: 'PRINT', 'GRAPHING', and 'START UP'. The 'START UP' button is circled in red, and a red arrow points to it from the text 'Click START UP'. Below the buttons is a large graph area with a vertical y-axis from 0 to 100 and a horizontal x-axis from 0 to 102. At the bottom of the window are 'EXIT' and 'SUBMIT' buttons. The Windows taskbar at the very bottom shows the 'start' button, the application title 'eSP P05575 Selec...', and the system clock '11:47'.

Click Yes to Synchronize Dialog



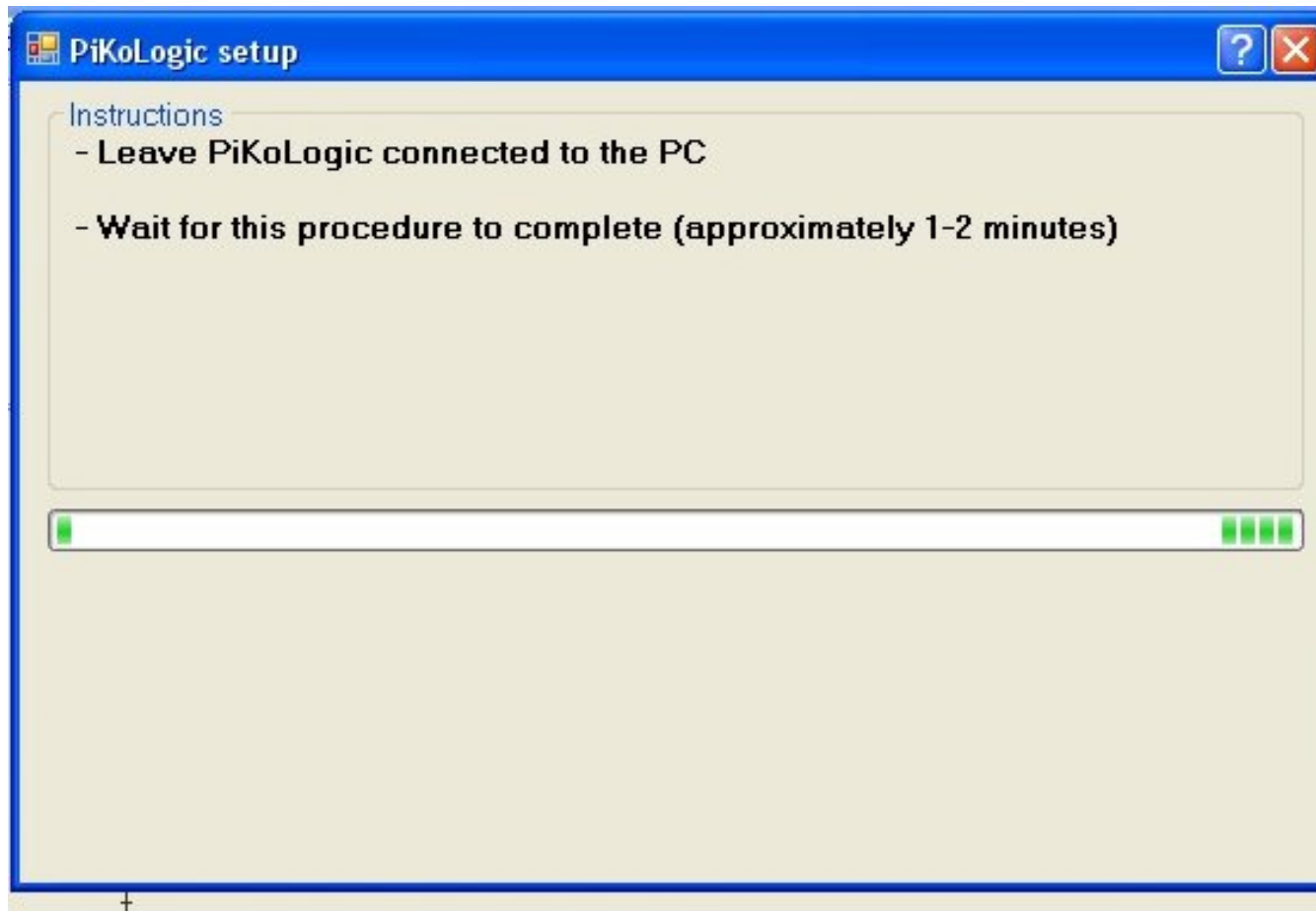
Click Start PiKoLogic setup



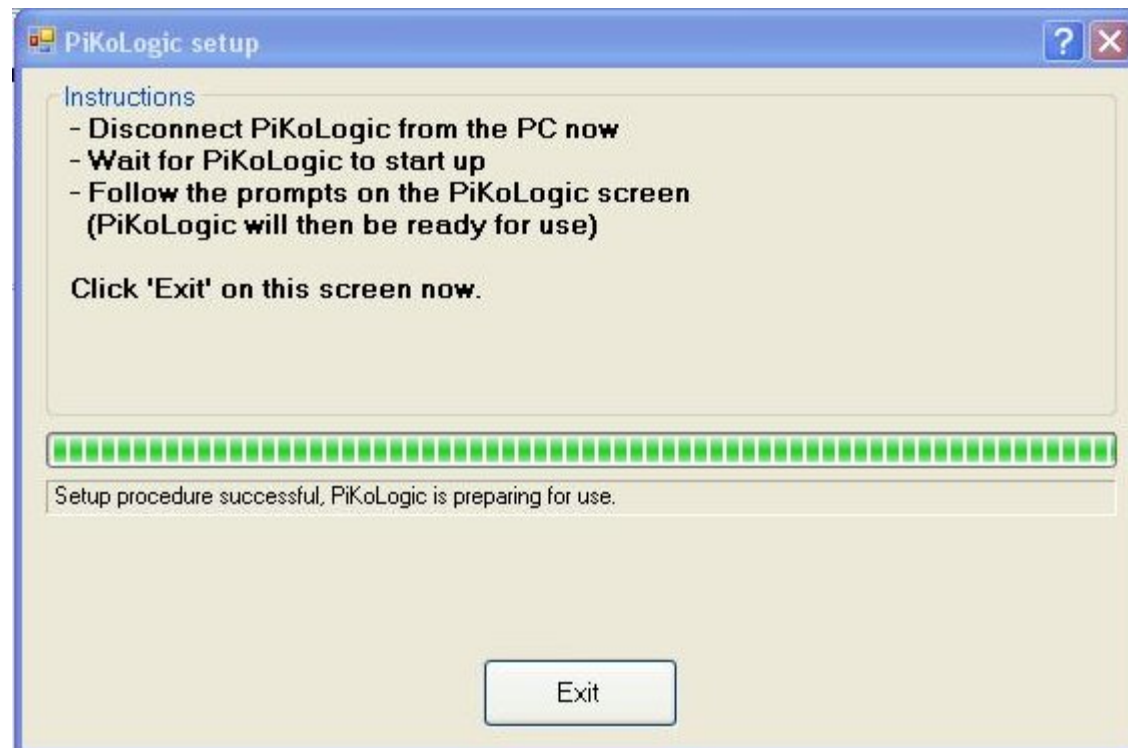


Step 2D

INSPIRING RESPIRATORY HEALTH



- When prompted, disconnect PiKoLogic from computer





Step 3 – Subject PIN

INSPIRING RESPIRATORY HEALTH

- Wait for PiKoLogic to complete start up
- Follow prompts

Do you want to enter a subject PIN now?

Yes No

Enter a PIN:

1111

1	2	3
4	5	6
7	8	9
Bksp	0	

Next>



Step 4 – PiKo-1

INSPIRING RESPIRATORY HEALTH

The PiKo setup procedure follows.

- If the subject's PiKo is available now, you must perform the PiKo setup now.
- If the PiKo is not available now, PiKo setup must be performed later by the subject.

Is the subject's PiKo available now?

Yes

No

- After clicking yes, place PiKo into cradle
- Press PiKo power button



Assignment Complete

INSPIRING RESPIRATORY HEALTH

Now:

2:26 PM

(Mountain Daylight Time)

Saturday
8/30/2008

Next alarm:

6:00 PM

Saturday
8/30/2008

AC power:

System battery:

PiKo battery:

Signal strength

Connected

PiKoLogic Status Screen



Tips

INSPIRING RESPIRATORY HEALTH

- Make sure computer is connected to internet
- PiKoLogic is fully charged (if not, plug in charger when disconnected from computer)
- Batteries properly installed in PiKo (check LCD screen by pushing power button)
- Don't work with the PiKoLogic in direct sunlight (strong light interferes with PiKo communication)
- Wait for prompts and follow prompts

Demonstration and Practice





Thank you

INSPIRING RESPIRATORY HEALTH

Questions ?